

REMARKS

Favorable consideration of the subject application is respectfully requested in view of the above amendments and following remarks. This amendment and reply is responsive to the non-final Office action mailed March 5, 2008. A Petition for an Extension of Time of two months and the requisite fee accompany this filing.

Claims 2-5, 9, 10, 16, 19, 23, 28-33, 35 and 36 have been amended and claims 37-42 have been added. Following the above amendments, claims 2-5, 9, 10, 16, 17, 19, 23, 28-33 and 35-42 are pending in the application, with claims 37, 38, 39 and 42 being in independent format.

Newly added claim 37 recites an interventional catheter assembly comprising an operating head coupled to a drive shaft and a drive assembly for rotation; a catheter system coupled to the operating head and with a control pod and including a sealed lumen for aspiration of debris and a sealed lumen for infusion of fluids, wherein the control pod houses the drive assembly for rotating the operating head and has an operator adjustment feature allowing an operator to increase and decrease the rotational speed of the drive shaft. Newly added independent claim 38 recites an interventional catheter system comprising an operating head coupled to a drive shaft for rotation, a catheter system communicating with the operating head and forming a sealed lumen, a control pod housing the drive assembly and an operator adjustment feature allowing the operator to change the rotational speed of the drive shaft, and a console unit providing power to the drive assembly and comprising a vacuum source providing vacuum for aspiration to the catheter assembly and an infusion source. Claims 2-5, 9, 10, 16, 19, 23, 28-33, 35 and 36 have been amended to change claim dependencies, to conform claim language to terminology provided in the new claims, and to incorporate subject matter previously recited in cancelled claims.

New claims 39-42 are directed to a console unit. Claim 39 recites a console unit for interfacing with an interventional catheter system having a cutter assembly for removal of material from a body lumen or cavity that implements control features based on an operator's input of parameters, wherein the console unit has an interface accepting the operator's input of parameters and has means for calculating and implementing automated operating conditions based on the parameters input by the operator. Claims 40 and 41 recite specific types of operator

input parameters and calculated and implemented automated operating conditions. New claim 42 recites a console unit for interfacing with an interventional catheter system having a cutter assembly for removal of material from a body lumen or cavity comprising a multi-lobed roller aspiration pump capable of providing constant, high levels of aspiration of liquids and/or liquid/debris mixtures and permitting fluid to flow in a conduit through rollers of the pump at atmospheric pressure.

It is submitted that all the above amendments are fully supported by the specification as originally filed and that none of the amendments constitutes new matter. These amendments are not being submitted for reasons of patentability and therefore do not give rise to prosecution history estoppel.

Double Patenting Rejection

Claims 1-5, 8-13, 16-17, 19-21 and 23-28 were alleged to conflict with claims of co-pending U.S. Application No. 10/798,621. The independent claims in the '621 application have been amended, and new independent claims are presented in the subject application. It is submitted that the independent claims maintain a clear line of demarcation between the applications and that the claims in the commonly owned, co-pending applications no longer conflict.

Claim Rejections – 35 USC § 103

Claims 1, 2, 4, 5, 9, 10, 12, 13, 16, 17 and 23-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (US 6,398,755) in view of Ross et al. (US 6,258,111). This rejection is respectfully traversed in view of the newly added and amended claims and the following remarks.

Belef et al. discloses a catheter and catheter drive unit providing controlled translation of a rotatable catheter core with an operative element, e.g. an atherectomy cutter, at its distal end. Translation displacement information is provided on displays on the catheter drive unit and the control unit. The control unit (6) may provide rotator drive on/off input, translator drive on/off input, rotation speed input and translation speed input. And, instead of inputting separate parameters, the control unit may be set up so that, if desired, once a procedure is chosen, the

procedure dictates, or suggests, the various operational parameters (i.e., rotational and translational speeds) to be used. The catheter drive unit and control unit are coupled through a two-way communication link. The sheath has a telescoping portion where it exits the housing of the catheter drive unit. Applicants do not perceive that the system of Belef et al. incorporates either an aspiration or an infusion system.

Ross et al. disclose a surgical cutting system for ophthalmic procedures incorporating a cutter for removing tissue and a vacuum source and aspiration port for removing cut material. The cutter operates by oscillating an inner sleeve past a window and the vacuum pressure pulls tissue into the port and inner channel. The motor is provided as part of the cutter apparatus. A gravity fed fluid irrigation system may also be provided. The speed of the cutter operation and the vacuum level in the aspiration line and the fluid irrigation system may be variable and controllable by the operator using a foot pedal.

Applicants' new claim 37 recites an interventional catheter assembly comprising an operating head coupled to a drive shaft and a drive assembly for rotation, a catheter system coupled at a proximal end with a control pod and at or near a distal end with the operating head, the catheter system including a sealed lumen for aspiration and a sealed lumen for infusion, wherein the control pod houses the drive assembly for rotating the operating head and incorporates an operator adjustment feature allowing an operator to increase and decrease rotational speed delivered to the drive shaft. Applicants' new claim 38 recites an interventional catheter assembly comprising an operating head coupled to a drive shaft and drive assembly for rotation, a catheter system forming a sealed lumen and communicating at a distal end with the operating head, a control pod housing the drive assembly and an operating adjustment feature providing adjustment of the rotational speed, and a console unit in electrical communication with the control pod and additionally comprising a vacuum source for aspiration and an infusion source.

Applicants do not acquiesce in the appropriateness of the combination of the Belef et al. and Ross et al. references and reserve their rights to present arguments, at a future time, that this combination is improper and/or inappropriate. For purposes of this response, Applicants do not perceive that the claimed combinations of features are disclosed or suggested by any combination of the Belef et al. and Ross et al. references relied upon for rejection. In particular, applicants do

not perceive that either Belef et al. or Ross et al. disclose or suggest a catheter or cutter system wherein a control pod houses both the drive assembly and an operator adjustment feature allowing an operator to increase or decrease rotational speed delivered to the drive shaft. Applicants also do not perceive that either Belef et al. or Ross et al. disclose or suggest a catheter or cutter system having a control pod housing the drive assembly and an operating adjustment feature providing adjustment of the rotational speed, and a console unit in electrical communication with the control pod and additionally comprising a vacuum source for aspiration and an infusion source. Withdrawal of this outstanding rejection is respectfully requested.

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (US 6,398,755) in view of Ross et al. (US 6,258,111) and further in view of Fine et al. (US 5,358,509). This rejection is respectfully traversed in view of the following remarks.

The Examiner has pointed to Col. 16, lines 36-45 of Fine et al. for a teaching of adjusting the current under load if the voltage is insufficient to produce the specified rotational output. Applicants do not interpret this disclosure as teaching that current delivered to the drive motor is adjusted, under load conditions, if the voltage for any specified rotational output is insufficient to produce the specified rotational output under load. And, Applicants furthermore submit that the Fine et al. reference does not overcome the deficiencies of Belef et al. and Ross et al. with respect to applicants' independent claims and further submit that the combination of features specified in claim 3 is not disclosed or suggested by any combination of the prior art references relied upon for rejection. Withdrawal of this rejection is respectfully requested.

Claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (US 6,398,755) in view of Ross et al. (US 6,258,111) and further in view of Valley et al. (US 5,795,325). Claim 8 has been cancelled.

Claims 11 and 31-33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (US 6,398,755) in view of Ross et al. (US 6,258,111) and further in view of Nash et al. (US 6,080,170). Claim 11 has been cancelled. The rejection of claims 31-33 is respectfully traversed in view of the newly added and amended claims and the following remarks.

Nash et al. disclose a lumen-opening catheter with a rotatable working head, a debris blocking member located distally of the working head and a fluid flow system for introducing an infusate and removing that liquid at a different flow rate to create a differential flow adjacent the working head. Applicants submit that the Nash et al. reference does not overcome the deficiencies of Belef et al. and Ross et al. with respect to applicants' independent claims and further submit that the combination of features specified in claims 31-33 is not disclosed or suggested by any combination of the prior art references relied upon for rejection. Withdrawal of this rejection is respectfully requested.

Claims 19-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (US 6,398,755) in view of Ross et al. (US 6,258,111) and further in view of Wulfman et al. (US 5,584,843). Claims 20 and 21 have been cancelled. This rejection, as it applies to pending claim 19, is respectfully traversed.

Applicants do not perceive that Wulfman et al. disclose a guidewire brake incorporated in a control pod and, furthermore, submit that the Wulfman et al. reference does not overcome the deficiencies of Belef et al. and Ross et al. with respect to applicants' independent claims and further submit that the combination of features specified in claim 19 is not disclosed or suggested by any combination of the prior art references relied upon for rejection. Withdrawal of this rejection is respectfully requested.

Claims 34-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (US 6,398,755) in view of Ritchart et al. (US 5,769,086). Claim 34 has been cancelled. This rejection, as it applies to pending claims 35 and 36, is respectfully traversed.

Ritchart et al. disclose a core biopsy device programmed to move a piercing needle automatically to a target tissue lesion, as well as to control the rotational orientation of the piercing needle. Applicants do not perceive that Ritchart et al. disclose or suggest the control features specified in pending claims 35 and 36 and submit, furthermore, that the Ritchart et al. reference does not overcome the deficiencies of Belef et al. and Ross et al. with respect to applicants' independent claims. Withdrawal of this rejection is respectfully requested.

Conclusion

In view of the above amendments and remarks, applicants believe that the pending claims are now in condition for allowance. Early consideration and allowance of all the pending claims are respectfully requested.

Respectfully submitted,



Janet Sleath

Registration No. 37,007

Date: August 1, 2008
SPECKMAN LAW GROUP PLLC
20601